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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,151	10/27/2003	Stephen C. Porter	03-116 (US01)	6462

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EXAMINER	
HOUSTON, ELIZABETH	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,151	PORTER, STEPHEN C.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 27 October 2003.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-40 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 27 October 2003 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 102703.031005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 18 states "between 100% and 200%, however the specification states on page 18 "between 110% and 200%.

Drawings

2. The drawings are objected to because axially oriented element (3) as stated on page 10 of the specification is not shown in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 29 is objected to because of the following informalities: Typo on line 2 "expands contracts". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a device that is swollen with an aqueous ionic solution outside the body and then is contracted when in contact with blood*, does not reasonably provide enablement for *a device with an active element that is swollen with a non-aqueous solvent that will diffuse out of the gel upon contact with blood and expands when placed in the body.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 1 states that the active element expands *or* contracts when placed in the body. Claim 27 is an embodiment of the invention that only contracts when placed in the body. Therefore the specification is not enabling.

6. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a device with an active element that is swollen with an aqueous ionic solution outside the body and then is contracted when in contact with blood*, does not reasonably provide enablement for *a device with an active element that is swollen with a non-aqueous solvent that will diffuse out of the gel upon contact with blood and expands when placed in the body.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 30 states that the active element expands when placed in the body. Claim 31 is an embodiment of the invention that only contracts when placed in the body. Therefore the specification is not enabling.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 4-8, 14-18, 24, 28-30, 32, 33, 36 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al. (USPN 6,723,108).

9. Jones discloses a vaso-occlusive device comprising an occlusive member that is a coil having a lumen (20) and an active element with an elongate shape carried in the lumen (22, Fig. 2B, Col 5, line 31). The active element is secured to the occlusive member at one or both ends and at one or more locations along the length of the occlusive member. The active element is a hydrogel that comprises a polymer that is polyvinylpyrrolidone (Col 5, line 26). The active element expands to have a cross-sectional dimension between 100% and 200% of the inter diameter of the occlusive member. The active element can be fibers (Col 5, line 34) comprising proteins (Col 5, line 52). The active element will expand within *about* 10 to 20 minutes after being placed in a body. As to claim 32, it is inherent that the active element will contract after being placed in the body depending on the initial state of the active element. For example, if the active element is in an already hydrated to an expanded state outside the body, it will contract after being placed in the body due osmosis and the change in the environment surrounding the active element.

10. Claims 1, 6,14-16, 30, 32, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Sepetka (USPub 2002/0169473).

11. Sepetka discloses an occlusive member in the shape of a coil having a lumen (352,354) and an active element (hydrogel) with an elongate shape that expands or contracts when placed in the body (368,370). The coil retains its shape when it is deployed in a body cavity. As to claim 32, it is inherent that the active element will contract after being placed in the body depending on the initial state of the active

element. For example, if the active element is in an already hydrated to an expanded state outside the body, it will contract after being placed in the body due osmosis and the change in the environment surrounding the active element.

12. Claims 1, 2, 4-6, 10, 12, 14-17, 19, 20 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferrera et al. (USPN 6,616,617).

13. Ferrera discloses vaso-occlusive device comprising an occlusive member that is a coil having a lumen (Fig. 10) and an active element with an elongate shape carried in the lumen (48). The active element is secured to the occlusive member at one or both ends and at one or more locations along the length of the occlusive member. The active element is a hydrogel comprising collagen or lactic/glycolic acids, a shape memory alloy or a shape memory polymer (Col 6, lines 25-35 and Col 13, lines 40-51).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 7-11, 17, 18, 21-29, 31, 32, 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sepetka in view of Sawhney (US Pub 2001/0046518).

16. Claims 9-11, 21-23, 25, 26, 27, 31, 34, 35, 37 and 3239 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones in view of Sawhney (US Pub 2001/0046518).

17.

18. Sepetka and Jones disclose the invention substantially as claimed as stated above except for the material that makes up the hydrogel.

19. Sawhney discloses a hydrogel used for occlusion of a body lumen. The hydrogel comprises polypropylene glycol or poly-hydroxyalkyl methacrylate (Para 37,38). The hydrogel comprises polysaccharides, hyaluronic acid or heparin (Para 35). The hydrogel further comprises chemical cross-linking agents (Para 31). The hydrogel is thermoresponsive (Para 40). The hydrogel comprises a polyelectrolyte (Para 38) and undergoes an ionic concentration induced shape change (Para 40). The active element can be a fiber (Para 37 and 62), which undergo a thermally induced phase change or a pH induced phase change (Para 40). The active element expands within about 10-20 minutes of being placed in a body and will increase to between 100 and 200 percent of the internal diameter of the coil (when the coil is undeployed) (Para 28).

20. As to claims 27, 31, 32, 38 and 39, when the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, *the hydrogel is comprised of a polyelectrolyte*) except for a property or function (in the present case, *the solvent*

will diffuse out of the gel upon contact with the blood causing the active element to contract) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

21. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the materials disclosed by Sawhney into the hydrogel of Sepetka and Jones. Sawhney provides the motivation in that the hydrogel disclosed provides advantages over prior art hydrogels. For example, they undergo a relatively large degree of swelling and hydrate relatively quickly with out degradation of mechanical properties (Para 23, 25). The inventions are analogous with each other and the instant invention and therefore the combination is proper.

22. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones and Sepetka in view of Sawhney as applied to claim 7 above, and further in view of Dieck et al. (USPN 6,953,465).

23. Jones and Sepetka in view of Sawhney disclose all the elements of the invention substantially as claimed except for the hydrogel comprising one or more polyester of alpha-hydroxy acids.

24. Dieck discloses a hydrogel comprising polydiaoxanone, polyanhydride and polyorthester (Col 4, lines 47-51).

25. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate polydiaoxanone, polyanhydride or polyorthester into the hydrogel. Jones discloses the claimed invention except for polyvinylpyrrolidone instead of polydiaoxanone, polyanhydride or polyorthester. Sepetka in view of Sawhney discloses the claimed invention except for heparin instead of polydiaoxanone, polyanhydride or polyorthester. Dieck shows that polydiaoxanone, polyanhydride or polyorthester is an equivalent material known in the art. Therefore, because the polymers were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the polydiaoxanone, polyanhydride or polyorthester for the polyvinylpyrrolidone or heparin.

26. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jones.

27. As to claim 3, Jones teaches an active element is attached to an occlusive member but is silent as to how. The claimed phrase "secured to the occlusive member by an adhesive" is being treated as a Product by Process limitation. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

(citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
7/10/06.